

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM S.A.)
)
Plaintiffs/Counterclaim Defendants,)
)
v.)
)
SANDOZ, INC.,)
)
Defendant/Counterclaim Plaintiff)

CIVIL ACTION NO.:
3:07-cv-02762-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
)
Plaintiffs,)
)
v.)
)
TEVA PARENTERAL MEDICINES, INC., and)
TEVA PHARMACEUTICALS USA, INC.)
)
Defendants.)

CIVIL ACTION NO.:
3:07-cv-02837-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM S.A.,)
)
Plaintiffs/Counterclaim Defendants,)
)
v.)
)
DABUR ONCOLOGY PLC.,)
DABUR PHARMA LIMITED,)
)
Defendants/Counterclaim Plaintiffs.)

CIVIL ACTION NO.:
3:07-cv-02854-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
)
Plaintiffs,)
)
v.)
)
PHARMACHEMIE B.V.,)
TEVA PARENTERAL MEDICINES, INC., and)
TEVA PHARMACEUTICALS USA, INC)
)
Defendants.)

CIVIL ACTION NO.:
3:07-cv-03144-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
)
Plaintiffs/Counterclaim Defendants,)
)
v.)
)
EBEWE PHARMA GES.M.B.H. NFG.KG)
)
Defendants/Counterclaim Plaintiffs.)

CIVIL ACTION NO.:
3:07-cv-03164-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
)
Plaintiffs/Counterclaim Defendants,)
)
v.)
)
SUN PHARMACEUTICAL INDUSTRIES,)
LTD. and CARACO PHARMACEUTICAL)
LABORATORIES, LTD.,)
)
Defendants/Counterclaim Plaintiffs.)

CIVIL ACTION NO.:
3:07-cv-03411-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
))
Plaintiffs/Counterclaim Defendants,)
))
v.)
))
ACTAVIS TOTOWA LLC, ACTAVIS,)
INC., ACTAVIS GROUP HF.,)
))
Defendants/Counterclaim Plaintiffs.)
))

CIVIL ACTION NO.:
3:07-cv-03142-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
))
Plaintiffs,)
))
v.)
))
MUSTAFA NEVZAT İLAÇ SANAYII A.Ş.))
(a.k.a. MN PHARMACEUTICALS),)
PAR PHARMACEUTICAL COMPANIES, INC.,)
PAR PHARMACEUTICAL, INC.)
))
Defendants.)
))

CIVIL ACTION NO.:
3:07-cv-03143-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
SANOFI-AVENTIS,)
DEBIOPHARM, S.A.,)
))
Plaintiffs/Counterclaim Defendants,)
))
v.)
))
ABRAXIS BIOSCIENCE, INC.,)
))
Defendants/Counterclaim Plaintiffs.)
))

CIVIL ACTION NO.:
3:07-cv-03163-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
 SANOFI-AVENTIS,)
 DEBIOPHARM, S.A.,)
)
 Plaintiffs/Counterclaim Defendants,)
)
 v.)
)
 MAYNE PHARMA LIMITED, MAYNE)
 PHARMA (USA) INC., HOSPIRA AUSTRALIA)
 PTY LTD., AND HOSPIRA, INC.)
)
 Defendants.)
)
)

CIVIL ACTION NOS.:
 3:07-cv-03409-JAP-JJH
 3:07-cv-04550-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
 SANOFI-AVENTIS,)
 DEBIOPHARM, S.A.,)
)
 Plaintiffs/Counterclaim Defendants,)
)
 v.)
)
 PHARMACHEMIE, B.V., et al.,)
)
 Defendants.)
)
)

CIVIL ACTION NO.:
 3:07-cv-02837-JAP-JJH

SANOFI-AVENTIS U.S. LLC,)
 SANOFI-AVENTIS,)
 DEBIOPHARM, S.A.,)
)
)
 Plaintiffs/Counterclaim Defendants,)
)
 v.)
)
 BARR LABORATORIES, INC.,)
 PLIVA-LACHEMA A.S.)
)
 Defendants/Counterclaim Plaintiffs.)
)
)

CIVIL ACTION NO.:
 3:08-cv-00079-JAP-JJH

**MEMORANDUM
 OPINION**

HUGHES, U.S.M.J.

I. INTRODUCTION

This matter has come before the Court upon letter application by Defendant Mayne Pharma Limited ("Defendant Mayne") seeking leave to file a summary judgment motion related to its claim of invalidity based on anticipation. The Court had previously entered a case management order stating that dispositive motion practice would be addressed at a status conference on September 22, 2008. Defendant Barr Laboratories, Inc. ("Defendant Barr") joins Defendant Mayne's request. Plaintiffs Sanofi-Aventis U.S. LLC, et al., ("Plaintiffs") and Defendants Sandoz, Inc., Actavis Totowa LLC, Abraxis Bioscience, Inc., Sun Pharmaceutical Industries, Ltd., and Caraco Pharmaceutical Laboratories, Ltd. (collectively "the '874 Defendants") oppose Defendant Mayne's request. For the reasons stated herein, Defendant Mayne's letter application is granted.

II. FACTUAL AND PROCEDURAL BACKGROUND

This litigation arises from Plaintiffs' complaint against Defendants for alleged patent infringement of its brand drug product, oxaliplatin. (Miller Ltr. dated May 7, 2008 at 2.) Plaintiffs brought action under 35 U.S.C § 271(e)(2) on the basis of the filing of an Abbreviated New Drug Application (ANDA) by the various defendants for the generic version of oxaliplatin. *Id.* at 3. These cases have been consolidated for purposes of discovery and case management. In all of the consolidated cases, Plaintiffs have asserted claims for infringement of either U.S. Patent No. 5,338,874 ("the '874 Patent") alone or claims for infringement of the '874 Patent and U.S. Patent No. 5,716,988 ("the '988 Patent"). *Id.*

A. Defendant Mayne

Defendant Mayne claims that a prior patent, the Kidani '846 Patent, anticipates, and thus invalidates, Plaintiffs' '874 Patent. (See Gross Ltr. dated May 13, 2008, Ex. B at 1.) In addition,

Defendant Mayne argues that the burden is on Plaintiffs to prove otherwise. *Id.* As Defendant Mayne faces infringement allegations on the '874 Patent alone, a successful summary judgment motion on the anticipation defense would resolve the entire case against it (and incidentally permit immediate market entry for its generic version). (Gross Ltr. dated May 13, 2008 at 1.)

Accordingly, Defendant Mayne proposes expedited resolution of its anticipation defense by summary judgment motion. Defendant Mayne argues that addressing the Kidani anticipation issue at this juncture is just and favors judicial economy. (Gross Ltr. dated May 13, 2008, Ex. B at 2-3.) Moreover, it would not prejudice any of the other Defendants nor the Plaintiffs by negatively impacting the orderly progression of discovery. *Id.* In addition, Defendant Mayne argues that allowing for early resolution will save the public up to \$40 million per month and nearly \$500 million per year on an important cancer medication by allowing consumers to benefit from the introduction of cheaper, generic drugs, thereby carrying out the purpose of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"). (Gross Ltr. dated May 13, 2008 at 1.)

Plaintiffs Sanofi-Aventis and Defendants Sandoz, Inc.; Actavis Totowa LLC; Abraxis Bioscience, Inc.; Sun Pharmaceutical Industries, Ltd.; and Caraco Pharmaceutical Laboratories, Ltd. argue that Defendant Mayne's request for expedited motion practice on the anticipation defense on the '874 patent would be premature, duplicative, inefficient, and unduly burdensome for both the Court and the parties. (Thompson Ltr. dated May 13, 2008 at 1.) They argue that it would also be prejudicial to all of the '874 Defendants. *Id.*

Defendant Mayne states that allowing its request is fair and favors judicial economy, noting that if its anticipation defense is successful, over half of the defendants will no longer be part of the various lawsuits. *Id.* Further, Defendant Mayne argues that there would be no prejudice to any of the other defendants or defense arguments – including, for example, any

obviousness defense – regardless of the Court’s decision on the anticipation issue. *Id.*

Defendant Mayne also argues that granting its request would not result in duplication of discovery as “[t]he expert discovery proposed here would not impact the schedule already set by the Court, and it will have to be done in the case anyway, so there is no wasted effort.” *Id.* (emphasis added).

B. Defendant Barr

Similar to Defendant Mayne, Defendant Barr faces infringement allegations only on the '874 Patent, meaning that success on the anticipation defense would resolve its case (and again, permit immediate market entry). (Miller Ltr. dated May 14, 2008 at 2). In addition, both Defendants have filed an ANDA on a solution product and both believe they are entitled to statutory "first-filer" exclusivity if, and when, the cases here are dismissed. *Id.*

Defendant Barr believes that Defendant Mayne's expert report, which was already produced, presents a straight-forward experiment that conclusively establishes that the Kidani '874 Patent enables optically pure oxaliplatin, therefore, anticipating the '874 Patent. *Id.* at 1. Defendant Barr echoes Defendant Mayne’s arguments that the burden is on Plaintiffs to prove the non-enablement of the Kidani '846 Patent. *Id.* Defendant Mayne argues that Plaintiffs "must show that it would require undue experimentation for a person of skill in the art to follow Kidani and succeed", a finding it alleges Plaintiffs will be unable to make. (Gross Ltr. dated May 13, 2008, Ex. B at 2 citing *Kalipharma, Inc. v. Bristol-Myers Co.*, 707 F. Supp. 741, 755 (S.D.N.Y. 1989)). Defendant Barr also cites the public's strong interest in obtaining access to low cost generic drugs, specifically life-prolonging cancer treatments, as a compelling argument for allowing Defendant Mayne to file its summary judgment motion. *Id.* at 2 (*quoting Kalipharma, Inc. v. Bristol-Myers Co.*, 707 F. Supp. at 756 ("[w]here there is a strong challenge to the patent's validity, the public interest calculus favors opening the generic market and achieving the 'cost

benefits to the public of generic drugs")). In addition, Defendant Barr argues that if Defendant Mayne is allowed to proceed and is successful, the cases against the '874-only defendants will be quickly terminated, thus considerably narrowing the issues and the parties to the case. *Id.* at 3.

C. Plaintiffs Sanofi-Aventis, et al.

Plaintiffs oppose Defendant Mayne's request, alleging that Defendant Mayne's arguments fail to meet the anticipation standard, that the amount of discovery necessary is substantial, and the proposal is burdensome and inefficient. Plaintiffs claim that Defendant Mayne's argument must be based on inherent anticipation. (O'Shaughnessy Ltr. dated May 13, 2008, Att. 1 at 1.) Plaintiffs further argue that Defendant Mayne's inherent anticipation argument fails, leaving it with an obviousness defense that would require several fact intensive considerations. *Id.* Plaintiffs state that it will likely take several months to obtain the requested information, review that material, and then depose the relevant witnesses before Plaintiffs would be in a position to respond to Defendant Mayne's reports. *Id.* at 3. Consequently, Plaintiffs argue that not much will be gained from a timing perspective by allowing Defendant Mayne to expedite its dispositive motion. *Id.* Plaintiffs further argue that Defendant Mayne's proposal will prolong discovery, the scope of the expert discovery will not be limited, Plaintiffs will be prejudiced by the possible lack of preclusion, and Defendant Mayne's proposal would result in piecemeal litigation which will inevitably result in inefficient case management. *Id.*

D. Defendant Sandoz

Defendant Sandoz joins Plaintiffs in opposing Defendant Mayne's request for expedited proceedings on the anticipation defense on the '874 patent. (Thompson Ltr. dated May 13, 2008.)

E. Defendants Actavis, Abraxis, Sun, and Caraco ("the '874 Defendants")

Defendant Actavis argues on behalf of Actavis Totowa LLC; Abraxis Bioscience, Inc.; Sun Pharmaceutical Industries, Ltd.; and Caraco Pharmaceutical Laboratories, Ltd. that "[i]f

Mayne is allowed to pursue 'piecemeal' litigation of a single [anticipation] defense at this stage of the proceedings, it will unnecessarily complicate this process during the very months that the parties are attempting to conduct a significant number of depositions as well as complete all remaining written discovery." (Baker Ltr. dated May 13, 2008 at 2.) Further, the '874 Defendants state that "the risk to the certainty of the current schedule far outweighs any likelihood that Mayne's proposal might result in a faster resolution of these cases by any significant amount of time." *Id.* Finally, the '874 Defendants oppose Mayne's proposed schedule on the grounds that it will lead to overlapping discovery and possible preclusion issues. *Id.* at 3. They argue that it would be highly prejudicial to the '874 Defendants if the Court allows Mayne to proceed with its anticipation defense. *Id.*

III. DISCUSSION

Defendant Mayne argues that their request for expedited proceedings on the anticipation defense would in this case promote efficient case management of eleven related cases and that an early resolution of at least some of these cases may result in tangible benefits to the public. The Court agrees.

A. Filing a Motion for Summary Judgment

Pursuant to Federal Rule of Civil Procedure 56(b), "[a] party against whom relief is sought may move *at any time* ... for summary judgment on all or part of the claim." Fed. R. Civ. P. 56(b). (emphasis added). In assessing whether to allow a motion for summary judgment, the Court notes that "[r]ather than endless pleadings 'served back and forth ad infinitum until the last issue of fact was tracked down' ... modern civil procedure instead 'relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims.'" *Doe v. Abington Friends Sch.*, 480 F.3d 252 (3d Cir. 2007) *quoting Swierkiewicz v. Sorema*, 534 U.S. 506, 512 (2002). In addition, "the Supreme Court has

explained that "[a]ny potential problem with ... premature [summary judgment] motions can be adequately dealt with under Rule 56(f)." *Doe*, 480 F.3d at 257 *quoting Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1986).

Here, the Court finds it is appropriate for Defendant Mayne, pursuant to Federal Rule of Civil Procedure 56(b), to file its motion for summary judgment on its anticipation defense.

Defendant Mayne proposes the following schedule regarding its anticipation defense:

- (1) Filing of the Motion for Summary Judgment to be due on November 10, 2008;
- (2) Opposition to the Motion to be due on December 9, 2008;
- (3) Reply in Support of Motion to be due on December 23, 2008; and
- (4) Suggested Oral Argument on the Motion for Summary Judgment in late January or February 2009.

The Court essentially adopts Defendant Mayne's proposed schedule as it is in almost perfect alignment with the schedule the Court has already set. (*See* Or. dated October 23, 2007 at 5 [dkt. entry no. 18] ("a [s]tatus conference[] will be held on September 22, 2008 at 2:00 P.M. to discuss dispositive motion practice/expert discovery")).

B. Inherent v. Express Anticipation Defenses

Defendant Mayne and Plaintiffs disagree as to whether an anticipation defense can successfully be resolved by summary judgment. Defendant Mayne argues that "[its expert report] presents a straight-forward experiment that conclusively establishes that the Kidani '846 Patent enables optically pure oxaliplatin and, therefore, anticipates the '874 Patent." (Miller Ltr. dated May 14, 2008 at 1.) They further argue that the burden is on Plaintiffs to prove otherwise.

Plaintiffs argue that to prove anticipation, Defendant Mayne must show that each limitation is found either expressly or inherently in a single prior art reference. As the Kidani

patent does not expressly state that the oxaliplatin made using its process is optically pure, Plaintiffs argue that Defendant Mayne's argument must be based on inherent anticipation. They further argue that Defendant Mayne's inherent anticipation argument fails, leaving it with an obviousness defense. Parenthetically, the court notes that, ordinarily, the mere existence of competing expert opinion dispels resolution by summary judgment.

However, the Court will not address the merits of Defendant Mayne's summary judgment claim, but rather only whether Defendant Mayne may file it. The Court finds that while the parties disagree as to whether the anticipation defense will succeed, Defendant Mayne has a colorable defense susceptible to resolution by summary judgment now rather than later. Defendant Mayne argues that Plaintiffs "must show that it would require undue experimentation for a person of skill in the art to follow Kidani and succeed," a finding it alleges Plaintiffs will be unable to make. (Gross Ltr. dated May 13, 2008, Ex. B at 2.) The Court finds that this argument, compounded with Defendant Mayne's arguments that success on its anticipation defense would result in over half the defendants no longer being parties to the lawsuit, no further expert discovery, no trial on the '874 Patent, and savings to the public of up to \$40 million per month and nearly \$500 million per year, provide compelling reasons for granting Defendant Mayne's request for expedited proceedings on their anticipation defense.

C. Federal Rule of Civil Procedure 16

Pursuant to Federal Rule of Civil Procedure 16(b)(4), "[a] schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4).

Here, the Court finds that public policy considerations and efficient case management practices *in this case* compel a finding of good cause pursuant to Rule 16(b)(4) sufficient to amend the Scheduling Order so that Defendant Mayne can file its summary judgment motion on the single issue of anticipation. Further, the Court finds that allowing Defendant Mayne to

proceed on summary judgment will promote judicial efficiency by allowing it to obtain the relief sought without burdening the court system, thus providing additional good cause sufficient to amend the Scheduling Order.

D. Federal Rule of Civil Procedure 1

Pursuant to Federal Rule of Civil Procedure 1, "[the Federal Rules] should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1. In the Court's experience, effective case management usually permits reasonable and focused discovery to be followed by, unless settled, a plenary summary judgment motion practice and/or trial. This process allows for guards against a fragmented motion practice which results in unnecessary costs to the litigants and multiple decision making for the court. In addition, "overuse" of summary judgment can prejudice the litigant who has limited resources to pursue its claim or defense.

However, where a party can make the case that an earlier, single issue summary judgment motion (which may deviate from the already set schedule) can resolve, or considerably streamline, the litigation, a court should exercise its discretion by allowing such a motion to proceed. The Court finds that allowing Defendant Mayne the opportunity to file its motion on this single issue may lead to a less expensive, expeditious, and just determination of this relatively complex litigation.

IV. CONCLUSION

For the reasons stated above, Defendant Mayne's request to file their Summary Judgment motion with respect to its claims of invalidity based on anticipation is granted. An appropriate Order accompanies this Memorandum Opinion.

Dated: June 12, 2008